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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/600,674	06/20/2003	Robert G. Aslanian	AL01583K1	6070
24265	7590	10/19/2004	EXAMINER	
SCHERING-PLOUGH CORPORATION PATENT DEPARTMENT (K-6-1, 1990) 2000 GALLOPING HILL ROAD KENILWORTH, NJ 07033-0530			CHANG, CELIA C	
			ART UNIT	PAPER NUMBER
			1625	

DATE MAILED: 10/19/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/600,674

Applicant(s)

ASLANIAN ET AL.

Examiner

Celia Chang

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 03 August 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) 20-24 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 17-19 is/are rejected.
- 7) ☐ Claim(s) 1-16 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

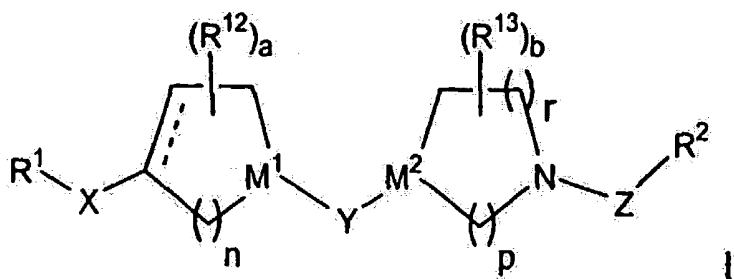
DETAILED ACTION

1. Response and election of group I, claim 15 and claims 1-14, 16 reading on the elected compounds and claims 17-19 for the method of treating congestion with partial traverse of the method restriction in the reply filed on Aug. 3, 2004 is acknowledged. The partial traversal is on the ground that other patents have allowed multiple methods. This is not found persuasive because the current state of the art in disease treatment is pathology and compound oriented. While a compound showing efficacy in variation of pathologies can receive patentability in multiple specific method claims, no nexus showing that all the compounds encompassed by the instant elected subgenus having nexus to all the utility of claims 17-19. The only data present in the specification is receptor binding and its preferred range with a single K_i of example 5 (see p.48). Please note that such information provided no nexus to the multiple utility of claims 17-19. Receptor binding without specific limitation and nexus to art recognized utility are considered reach through claims (see Baker Botts "In print").

The requirement is still deemed proper and is therefore made FINAL.

Based on the election, claims 1-16, the compounds and composition together with method of treating congestion using the elected compounds of following:

A compound selected from formula I as following:



wherein

a is 0-3;

b is 0-3;

n is 2;

p is 1 or 2;

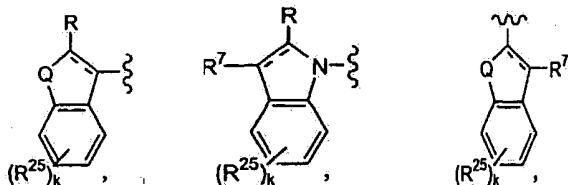
r is 0, 1, or 2 and that the sum of r and p is 2;

$$M^1 \text{ is } \mathbb{N}, M^2 \text{ is } \mathbb{C}R^3;$$

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Y is C=O, C=S, (CH₂)_q, C(O)NR⁴, C(O)CH₂, SO₁₋₂, or C(=N-CN)-NH;X is a bond or C₁₋₆ alkylene;

q is 1-5;

R¹ isQ is NR⁸;

k is 0-4;

R, R², R³, R⁴, R⁷, R⁸ and Z are as defined in claim 1, are examined.

The remaining subject matter of claims 1-19 and claims 20-24 are withdrawn from consideration per 37 CFR 1.142 (b).

2. Claims 17-18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is unclear what does the term "allergy-induced airway responses" mean. What are the conditions encompassed by this term? Please note that the term lacks antecedent basis in the specification and no description was found for this condition.

3. Claims 17-19 rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claims contain subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

As stated in the MPEP 2164.01(a) "There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is "undue". The factors to be considered herein are those set forth as the In re Wands, 8 USPQ 2nd 1400 (1988) decision.

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Nature of invention

The instant claims are drawn to treating distinct and diversified disease using the compounds of claims 1-15. In claims 17 both hyper and hypo motility, hyper-(cardiovascular disease) and hypo-tension, hyper and hypo-CNS activity are being treated. The treatments were described being the result of the compounds being histamine H3 antagonists (see page 1 specification). Screening procedure for histamine H3 receptor was disclosed on page 47-48 with one single Ki for example 5.

The state of the art and predictability

Applications described only the steps of receptor assay with compounds being screened by the assay are considered to be lacking of a specific description and enablement for method of treating conditions mediated by receptors (see Baker Botts). Further, it was evidenced that indolyl compounds useful in treating nasal congestion functions through the alpha-2-adrenoceptor mechanism. While compounds having H3 receptor activity and useful in treating nasal congestion do not have similar structure as the claims (see US5,217,986, 5,352,707). While relief nasal congestion without the alpha-adrenoceptor side effect, only combination of H1 and H3 receptor blockade can produce such result (see CA 136:48247).

The amount of guidance and working examples

In view of the above evidenced complexity in treatment of nasal congestion involving receptors and the lack of nexus between the instant claimed compound and treatment of nasal congestion, the disclosure of a single ki value for example 5 lacks description and enablement for the claims. The instant specification provided no guidelines as to how to pick and choose the various compounds with properties that correlate to the treatment of nasal congestion.

4. Claim 1-14, 16 are objected to because they contain the non-elected invention. It is recommended that the elected scope be incorporated into the base claim and any intervening claims. Claim 15 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

5. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The Terzioglu indolyl compound art.


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6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Celia Chang whose telephone number is 571-272-0679. The examiner can normally be reached on Monday through Thursday from 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang, can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

OACS/Chang
Oct. 15, 2004


Celia Chang
Primary Examiner
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